UNITED STATES DISTRICT COURT

DISTRICT OF MINNESOTA

PATRICIA ROBERSON, as Trustee for the heirs and next of kin of RAY ROBERSON, deceased, Plaintiff, v. MEDTRONIC CORPORATION, Defendants.	Court File No. 06cv3965 JMR/AJB **COMPLAINT AND DEMAND FOR JURY TRIAL**

ESTATE OF RAY ROBERSON (DECEASED)

NATURE OF THE CASE

1. Plaintiff Decedent Ray Roberson ("Plaintiff") died at age 62 as a result of his Medtronic implantable cardioverter defibrillator's ("ICD") mechanical failure. It has become apparent since Mr.Roberson's death that Medtronic knew or should have known of the defects within Mr. Roberson's device and the risks associated with his device.

2. Patricia Roberson is the statutory heir and survivor of Decendant Ray Roberson, and brings this claim for wrongful death and survival claims pursuant to Minn. Stat. Ann. 573.02 for all damages and claims authorized therein. Patricia Roberson is the surviving spouse of Plaintiff Decedant.

3. Medtronic, Inc. manufactures ICDs. The defibrillators are small devices about the size of a pager that are implanted into the chest cavity of patients and are intended to monitor irregularities in heart rhythm (arrhythmia). When functioning properly, ICDs are able to detect when the heart is beating out of rhythm and deliver a series of electrical shocks to correct the arrhythmia.

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U.S. DISTRICT COURT MPLS

4. On or about November 12, 2002, Plaintiff was implanted with a Marquis DR Model 7274 defibrillator manufactured by Defendant, Serial Number PKC103930H. On October 5, 2003, Plaintiff died of complications stemming from the device's failure.

5. In February 2005, Defendant issued an advisory with regard to Plaintiff's device, indicating the following:

> Medtronic Marquis family of ICD and CRT-D devices having batteries manufactured prior to December 2003 may experience rapid battery depletion due to a specific internal battery short mechanism.
>
> Highly accelerated bench testing indicated the rate of this shorting mechanism may increase as the battery is depleted. At the time of the mailing, the rate of shorting was approximately 1 in 10,000 (0.01%), bench test data indicated the rate may increase to between 0.2% and 1.5% over the second half of device life.
>
> There is no provocative testing that predicts which of these devices will experience this issue. Once a short occurs, depletion can take place within a few hours to a few days, after which there is complete loss of device function. It is also possible that as the battery depletes quickly, patients may experience temporary warmth in the area surrounding the ICD.

6. This lawsuit asserts claims against Medtronic, Inc. for negligence; strict product liability for manufacturing and/or design defect; strict product liability for failure to warn; breach of express and implied warranties for the design, manufacture, production, testing, study, inspection, labeling, marketing, advertising, sales, promotion, and distribution of the device model that caused Plaintiff's device to malfunction resulting in Plaintiff's death; and violation of Minnesota consumer protection law. The complaint also seeks recovery for loss of consortium on behalf of Plaintiff Patricia Roberson.

PARTIES

7. At all relevant times, Plaintiff was a resident and citizen of the state of Georgia and resides in Savannah, Georgia.

8. Defendant Medtronic, Inc. (Medtronic) is a corporation existing under the laws of Minnesota with its principal place of business in that state.

9. This Court has subject matter jurisdiction over this matter pursuant to 28 U.S.C. § 1332. The matter in controversy in this civil action well exceeds $75,000, exclusive of costs and interest, as to the defendant, and is between citizens of different states.

10. Venue is proper in this district under 28 U.S.C. § 1391 because defendant's business emanated from Minnesota.

FACTUAL ALLEGATIONS

11. On November 12, 2002, Plaintiff was implanted with a Marquis DR Model 7274 defibrillator that was developed, tested, marketed, warranted and sold by Defendant. This ICD is one of the Marquis family of devices about which Defendant issued advisories in February, 2005.

12. This case involves, *inter alia*, Defendant's failure to warn doctors and patients of information within its knowledge, possession or both indicating the subject ICDs were affected by a design and manufacturing defect that made them unreasonably dangerous, unfit for their intended use, and that they posed health risks (including in some cases the risks of death or serious injury) to ICD recipients.

13. Defendant designed, manufactured, marketed and sold the subject ICD, touting the device's exceptional design and reliability in monitoring, regulating heart rhythm, and reviving a person's heart during arrhythmia and/or arrest. Defendant omitted material facts, intentionally withheld information regarding device malfunctions and mechanical design defects, and failed to timely and adequately warn the medical community and the general public, thereby placing tens of thousands of people unnecessarily at risk without their informed consent.

Defendant's Device and Its Intended Functions

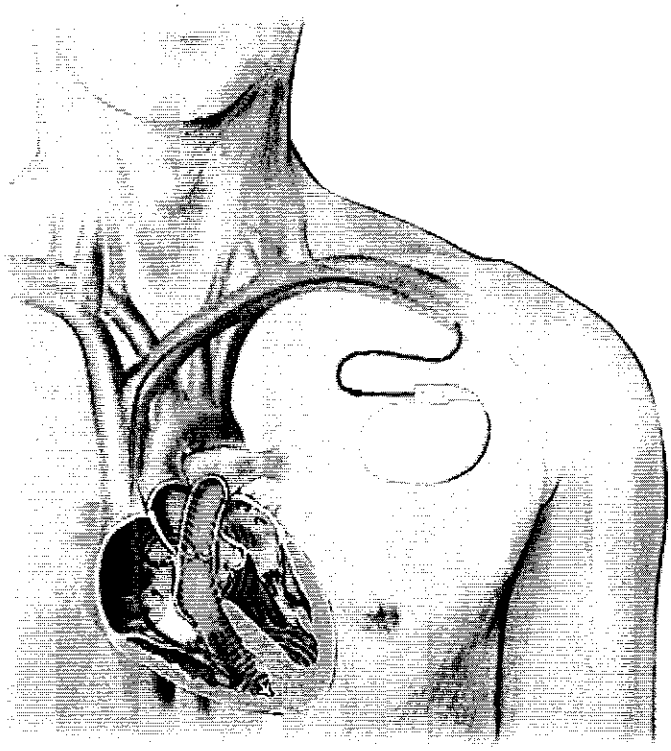
14. Cardiovascular disease is the leading cause of death in both women and men in the United States, claiming more lives every year than the five leading causes of death combined.

15. A normal heartbeat results from an electrical impulse originating in the sinoatrial (SA) node in the upper right chamber of the heart known as the atrium. The impulse causes the atria to contract, which then causes blood to fill the ventricles. The impulse then travels down to the ventricles causing them to contract, forcing blood out of the heart. This cycle repeats itself continuously, which results in a normal heartbeat.

16. An irregular heartbeat, or arrhythmia, results when the normal electrical system malfunctions. These arrhythmias can prevent the heart from pumping enough blood to the body, which can lead to physical symptoms, tissue death, and cardiac arrest.

17. Certain persons with an arrhythmia require an ICD to monitor and respond to their irregular heartbeat. Similar to a pacemaker, an ICD monitors, regulates, and stabilizes in the event of either an increase or decrease in heart rhythm. When a person's heart stops pumping normally, the ICD automatically determines what type of treatment is needed, if any, and delivers it automatically.

18. Medtronic manufactures several different ICD systems with different settings, features, and capabilities. All of these essentially include a pulse generator, which is a small unit about the size of a pager, and one or two electrical wires extending from the top, called leads. The device is implanted in the upper chest near the neck with the leads running to the heart via blood vessels. An ICD device and anatomical location is described in the following diagram:



19. The ICD is capable of pacing, or treating and correcting a heartbeat that is too slow (bradycardia) or too fast (tachycardia) by delivering a series of electrical impulses. The patient may not feel the pulses or it may feel like fluttering in the chest. It is painless.

20. The ICD is also capable of cardioversion. Cardioversion requires stronger electrical shocks than pacing, and it is designed to interrupt a harmful arrhythmia. Patients report cardioversion is uncomfortable.

21. The ICD is also capable of defibrillation. Defibrillation is the application of a high-energy shock to the patient's heart and is appropriate treatment for very fast and irregular heartbeats called ventricular tachycardia (VT) or ventricular fibrillation (VF). Patients with either VT or VF usually faint or become unconscious and do not feel the powerful shock delivered during defibrillation. However, if they are not unconscious and/or are not in VT or VF when the ICD discharges a shock, they most certainly do feel the shock, and experience tremendous pain.

22. During a heart failure episode, a patient's survival depends upon the success of the ICD device detecting the problem and shocking the heart back to a regular rhythm. Without a prompt response, a patient's life faces great peril, and may require external resuscitation from medically trained personnel. Every day, thousands of Americans rely on these devices to monitor their hearts and respond during a time of need.

23. If functioning properly, an ICD can save lives. If an ICD fails to engage during an arrhythmic episode, a patient in cardiac arrest has only minutes before permanent injuries or death occurs. The medical community often describes this concept as "time is muscle."

Patient's Medical History with Defendant

24. On November 12, 2002, Plaintiff was implanted with a Marquis DR Model 7274 defibrillator. Mr. Roberson was unaware of the design and/or manufacturing defect within his device, which was known or should have been known to exist by Defendant, at the time of his implantation surgery.

25. Mr. Roberson, dependent on the ICD for cardiac regulation and stabilization, relied on the mechanical success and function of his device on a daily basis.

26. On October 5, 2003, Mr. Roberson died. On information and belief, Mr. Roberson died as a result of his ICD's mechanical failure.

27. Defendant never directly, nor through any other means, informed Plaintiff about the risks associated with the design and/or manufacturing defects known to it, or about which it reasonably should have known, which existed in the ICD implanted into Plaintiff.

28. Defendant knew or should have known about the design and/or manufacturing defects associated with the ICD implanted in Plaintiff, and had a duty to inform him and all ICD recipients about the risks associated with the design and/or manufacturing defects of the device.

29. Plaintiff reasonably relied on Defendant's representations that the ICD implanted into him contained no design and/or manufacturing defects. Having not been informed about the design and/or manufacturing defects present in Defendant's ICD, Plaintiff chose to implant the ICD.

30. At all times relevant to Plaintiff's implantation, use, and injury from Defendant's ICD, Defendant never told Plaintiff about the risks associated with the design and/or manufacturing defects associated with the ICD implanted in him.

31. Therefore, unsuspecting of any design and/or manufacturing defect associated with Defendant's ICD, Plaintiff has been injured as a result of the failure of the ICD implanted in him.

CLAIMS FOR RELIEF
COUNT ONE
(Negligence)

32. Plaintiff realleges all previous paragraphs.

33. Defendant had a duty to exercise the care of an expert in all aspects of the manufacture, testing, inspection, packaging, labeling, distribution, marketing, sale, withdrawal and recall of the ICD, to insure the safety of its product and to insure that the consuming public, including the Plaintiff and their physicians and agents, obtained accurate information and instructions for the safe use or non-use of the ICD.

34. Defendant failed to discharge this duty by distributing a defectively designed and/or manufactured device into the stream of commerce without warning or notice of the defects. Defendant's failure to discharge its duty exposed Plaintiff to life threatening physical trauma, resulting in death. Defendant's failure to discharge its duty rendered Plaintiff's physicians ignorant of information necessary to treat Plaintiff.

35. In addition, Defendant made omissions and concealed material facts with the

understanding that patients and physicians would rely upon its statements when choosing Defendant's device. The economic damages and physical harm caused by Defendant's conduct would not have occurred had Defendant exercised the high degree of care imposed upon it and Plaintiff therefore pleads the doctrine of *res ipsa loquitur*.

36. As a direct and proximate result of Defendant's conduct, Plaintiff suffered and will continue to suffer economic loss, pecuniary loss, loss of companionship and society, mental anguish and other compensable injuries.

COUNT TWO
(Wrongful Death on Behalf of Heirs)

37. Plaintiffs incorporate by reference all preceding allegations as is fully set forth herein.

38. Plaintiffs allege, on information and belief, that Plaintiff's sudden, premature and untimely death was the result of the Decedent being implanted with the Marquis DR Model 7274 defibrillator.

39. As alleged throughout this Complaint and as incorporated herein, Plaintiffs allege that Decedent would not have suffered a premature and untimely death but for the intentionally and negligently tortious conduct of Defendants; similarly, as alleged throughout this Complaint and as incorporated herein, Plaintiffs allege the Defendants are strictly liable for Decedent 's death and all injuries and damages flowing from his death, for the reasons alleged in this Complaint.

40. Plaintiffs seek to recover damages for all legally compensable injuries relating to Plainitff's wrongful death.

COUNT THREE
(Strict Liability: Design and Manufacturing Defect)

41. Plaintiff realleges all previous paragraphs.

42. Defendant's ICD was defectively designed and manufactured because the

foreseeable risks of mechanical malfunction and failure outweighed the benefits associated with the device.

43. Defendant's ICD was expected to and did reach Plaintiff without substantial change or adjustment to its mechanical function upon implanting the device.

44. Defendant, the manufacturer of the ICD, knew or should have known of the design and/or manufacturing defect and the risk of serious bodily injury that exceeded the benefits associated with the design or formulation.

45. Furthermore, Defendant's ICD and its design and/or manufacturing defects presented an unreasonably dangerous risk beyond what the ordinary consumer would reasonably expect.

46. The ICD Defendant manufactured and supplied to Plaintiff was defectively designed and/or manufactured due to inadequate warnings or instruction because Defendant manufacturer knew or should have known through testing or otherwise that the product created a high risk of bodily injury and serious harm. Defendant failed to provide adequate and timely warnings of the risks to consumers, both before sale and post-sale.

47. As a direct and proximate result of Defendant's failure to warn and improper conduct Plaintiff suffered and will continue to suffer economic loss, pecuniary loss, loss of companionship and society, mental anguish and other compensable injuries.

48. Defendant's ICD is a product inherently dangerous for its intended use due to design and/or manufacturing defect and improper functioning. Defendant is therefore strictly liable to Plaintiff for damages specified herein.

COUNT FOUR
(Strict Liability: Failure to Warn)

49. Plaintiff realleges all previous paragraphs.

50. Defendant developed, manufactured, marketed, and distributed the ICD to the

general public even after learning of design defects that threatened the intended use of the device.

51. The ICD models with design and/or manufacturing defects were expected to and did reach Plaintiff without substantial change or adjustment to mechanical function upon implanting the device.

52. Defendant knew or should have known through testing, adverse event reporting, or otherwise, that the product created a high risk of bodily injury and serious harm.

53. Defendant failed in providing timely and adequate warnings or instruction regarding its devices it knew or should have known contained a design and/or manufacturing defect.

54. As a direct and proximate result of Defendant's conduct, Plaintiff suffered and will continue to suffer economic loss, pecuniary loss, loss of companionship and society, mental anguish and other compensable injuries.

55. Defendant's ICD is a product inherently dangerous for its intended use due to design and/or manufacturing defect and improper functioning. Defendant is therefore strictly liable to Plaintiff for damages specified herein.

COUNT FIVE
(Breach of Implied Warranty)

56. Plaintiff realleges all previous paragraphs.

57. At the time Defendant designed, manufactured, produced, tested, studied, inspected, labeled, marketed, advertised, sold, promoted, and distributed its ICD devices for use by Plaintiff, they knew of the use for which their devices were intended.

58. Defendant impliedly warranted its ICD products to be of merchantable quality and safe and fit for their intended use.

59. Contrary to this implied warranty, Defendant's ICD device was not of

merchantable quality, safe or fit for its intended use because the device was and is unreasonably dangerous and unfit for the ordinary purposes for which it was and is used, as alleged herein.

60. As a direct and proximate result of Defendant's conduct, Plaintiff suffered and will continue to suffer economic loss, pecuniary loss, loss of companionship and society, mental anguish and other compensable injuries.

COUNT SIX
(Breach of Express Warranty)

61. Plaintiff realleges all previous paragraphs.

62. Defendant's concealment and failure to warn through promotional statements and product literature expressly warranted to Plaintiff that the implanted ICD was safe, capable of reducing the risk or severity of heart failure, and was a highly reliable product in comparison to the conventional product line.

63. In response to these promises and express statements, Plaintiff and Plaintiff's physicians and surgeons relied on Defendant's affirmations and warranties.

64. The ICD did not conform to those express representations in light of recently discovered disclosures and information previously withheld by Defendant. Defendant's express warranty through its false statements failed to disclose and provide patient approval of the design and/or manufacturing defects inherent in the devices.

65. Defendant breached its warranty of the mechanical soundness of its ICD by continuing sales and marketing campaigns highlighting the safety of its product while it knew of the design and/or manufacturing defects and risk of product failure.

66. As a direct and proximate result of Defendant's breach of its express warranty, Plaintiff suffered economic losses, physical injuries, and other compensable damages.

COUNT SEVEN
(Misrepresentation by Omission)

67. Plaintiff realleges all previous paragraphs.

68. Defendant misrepresented the mechanical soundness and reliability of its ICD devices to the general public through promotional and marketing campaigns. Defendant continued this misrepresentation for an extended period of time without disclosing material information.

69. Defendant took advantage of Plaintiff's limited opportunity to discover Defendant's strategic and intentional concealment of the defects in its ICDs.

70. Defendant concealed these design and/or manufacturing defects from the public by withholding information pertaining to the inherent design and/or manufacturing defects and high risks of failure relating to Defendant's ICD, and presenting the devices as sound and reliable.

71. Defendant's intentional misrepresentations and omissions were made willfully, wantonly and/or recklessly to Plaintiff to induce the purchase of Defendant's ICD over other pacemaker/defibrillators on the market.

72. Defendant knew or should have known of the high risk Plaintiff would encounter by unwittingly agreeing to have implanted one of Defendant's defectively designed and/or manufactured devices.

73. As a direct and proximate result of relying upon Defendant's misrepresentations, Plaintiff suffered and will continue to suffer economic loss, pecuniary loss, loss of companionship and society, mental anguish and other compensable injuries.

COUNT EIGHT
(Constructive Fraud)

74. Plaintiff realleges all previous paragraphs.

75. Defendant, while in possession of unique and pertinent information involving the safety and mechanical reliability of its ICDs, presented its ICD devices as mechanically sound and failed to warn of its inherent design and/or manufacturing defects. Defendant suppressed this information and continued sales and marketing of its ICDs to the general public. Defendant knew or should have known Plaintiff had no means, other than Defendant's full, accurate, and objective disclosure, of obtaining the relevant information.

76. Through its unique knowledge and expertise regarding the affected nature of the ICDs, and through its statements to physicians and their patients in advertisement, promotional materials, and other communications, Defendant professed and affirmed to Plaintiff its knowledge of the truth of the representation that its ICDs were safe for their intended use and were free from design and/or manufacturing defects.

77. Defendant made misrepresentations and omissions intentionally to induce Plaintiff to purchase Defendant's ICDs and to allow Defendant to reap the high profit margins associated with Defendant's affected ICD family of products.

78. Defendant engaged in conduct that took unconscionable advantage of its dominant position of knowledge and engaged in constructive fraud in its relationship with Plaintiff. Misled by this veil of fraud, the Plaintiff reasonably relied on Defendant's representations.

79. As a result, Plaintiff has suffered and will continue to suffer economic loss, pecuniary loss, loss of companionship and society, mental anguish and other compensable injuries.

COUNT NINE
(Violation of Minnesota False Statement in Advertisement Act)

80. Plaintiff realleges all previous paragraphs.

81. After learning of inherent design defects in its ICDs, Defendant produced and

published advertisements and deceptive and misleading statements concerning the soundness and mechanical reliability of its ICDs with the intent to sell its ICDs.

82. Defendant concealed its deceptive practices in order to increase the sale of and profit from its ICD devices.

83. Defendant violated Minn. Stat. § 325F.67 by intending to sell, and creating a customer demand for its ICD devices, using deceptive or untrue statements of fact about the devices' mechanical soundness and reliability. Defendant did so by use of its website and medical brochures distributed to patients and physicians.

84. The Minnesota statutes prohibiting false statements in advertising apply to all Plaintiff transactions with Defendant because Defendant's deceptive scheme was carried out in Minnesota and affected Plaintiff's implanted and defective device.

85. As a result of Defendant's practices, Plaintiff suffered actual damages. Plaintiff is entitled to recover those damages along with costs, expenses, and attorneys' fees pursuant to Minn. Stat. 8.31, subd. 3a.

COUNT TEN
(Violation of the Minnesota Prevention of Consumer Fraud Act)

86. Plaintiff realleges all previous paragraphs.

87. Defendant intentionally concealed its design and/or manufacturing defect and failed to disclose for the purposes of continuing the sale and distribution of its affected devices.

88. Defendant represented its ICDs as safe and effective and intended that patients and physicians rely on those representations when determining whether Defendant's ICD device was optimal for meeting the patient's needs.

89. Through these misleading and deceptive statements and false promises, Defendant violated Minn. Stat. § 325F.69.

90. The Minnesota statutes prohibiting consumer fraud apply to Plaintiff's transactions with Defendant because Defendant's deceptive scheme was carried out in Minnesota and affected Plaintiff, who was implanted with a device containing a design and/or manufacturing defect.

91. As a result of Defendant's practices, Plaintiff suffered and will continue to suffer economic loss, pecuniary loss, loss of companionship and society, mental anguish and other compensable injuries, and is entitled to recovery of those damages along with attorneys' fees. Minn. Stat. § 8.31, subd. 3a.

COUNT ELEVEN
(Loss of Consortium)

92. Plaintiff restates and realleges each and every allegation set forth in paragraphs 1 through 87.

93. Based on Medtronics liability to Ray Roberson for the claims made above, Patricia Roberson is entitled to recover damages for loss of consortium.

94. This cause of action is brought on behalf of Plaintiff, Patricia Roberson, the widow of Plaintiff Decedent, Ray Roberson. As a result of the causes of action set forth herein, the defective nature of the Medtronic ICD that was implanted in Mr. Roberson, and by reason of the injuries sustained by Mr. Roberson, including his untimely death, Plaintiff's wife, Patricia Roberson has suffered and will continue to be deprived of consortium, comfort and care resulting in extreme grief, anguish and mental distress.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff seeks judgment in her favor against the Defendant as follows:

95. Economic and non-economic damages in an amount in excess of $75,000 as provided by law and to be supported by the evidence at trial;

96. An award of attorneys' fees and costs of suit, as provided by law;

97. Such other legal and equitable relief as this Court deems just and proper.

PLAINTIFF HEREBY DEMANDS A JURY TRIAL.

DATED: Oct. 3, 2006

ZIMMERMAN REED, PLLP

By: _____

Charles S. Zimmerman, #120054
Ronald S. Goldser, #35932
Michael B. Sonsteng, #0309035
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ATTORNEYS FOR THE PLAINTIFF

STATE OF MINNESOTA

DISTRICT COURT

COUNTY OF HENNEPIN

FOURTH JUDICIAL DISTRICT
CASE TYPE: WRONGFUL DEATH

In the Matter of the Appointment of a Trustee for the heirs of Ray Roberson , Decedent.

Court File No.

ORDER APPOINTING INTERIM TRUSTEE

Based upon the Petition for Appointment of Trustee, Oath of Petitioner, and the executed Waivers of Notice of Bond for an order of formal appointment of Patricia Roberson as trustee, the undersigned Judge having heard and considered such Petition, being fully advised in the premises:

IT IS HEREBY ORDERED THAT, Patricia Roberson be appointed interim trustee to maintain the action described in said Petition and that she serve without bond pursuant to the written requests filed by next of kin Rayball Roberson, Jr, Donald Roberson and Barney Roberson and subject to the receipt of the Waivers of Notice and Waiver of Bond of Jessie Roberson and Teresa Roberson. This Order is entered to permit the trustee to commence a wrongful death action on behalf of decedent's heirs in *In re: Ray Roberson v. Medtronic* . If said Waivers are not filed by November 5, 2006, the Trustee shall file a bond in the amount of $1,000.00 (One Thousand and no/100 Dollars).

Dated:

10-03-06

BY THE COURT

Judge of District Court

OCT 0 3 2006

Harry S. Crump

ZIMMERMAN REED
ATTORNEYS AT LAW

4649 1

October 3, 2006

MICHAEL B. SONSTENG
Admitted in Minnesota
mbs@zimmreed.com

Via Hand Delivery

REPLY TO MINNEAPOLIS

Clerk of Court
U.S. Courthouse
300 South Fourth Street
Minneapolis, MN 55415

RE: Patricia Roberson v. Medtronic, Inc.

Dear Clerk of Court:

Enclosed for filing in the above-entitled matter, please find the following:

1. Civil Cover Sheet;
2. Summons;
3. Complaint; and
4. Order Appointing Trustee.

Please return a file stamped copy of the enclosed extra Complaint to our office with the original Summons. Also, enclosed please find our check in the amount of $350.00 for the filing fee.

Thank you for your assistance. If you have any questions, please feel free to contact me.

Very truly yours,

ZIMMERMAN REED, P.L.L.P.

Michael B. Sonsteng
MBS:mab

Enclosures

RECEIVED
06 OCT -3 PM 4:21
CLERK, U.S. DIST. COURT
MINNEAPOLIS, MN